

REMARKS

Claims 1-13, 17-19, 20, 21, 24 and 25 are currently pending. Claims 10, 20 and 21 have been amended. Claims 14-16, 22, 23 and 26 were withdrawn by the Examiner and are canceled without prejudice herein. Applicants submit that no new matter has been added by this amendment. Additionally, Applicants respectfully thank the Examiner for including claim 24 in Group I, which are currently under Examination. Applicants respond to the outstanding rejections as follows.

Rejections under 35 USC §101

Claims 20 and 21 are rejected under 35 USC §101 because the claimed invention is directed to non-statutory subject matter. As suggested by the Examiner, Applicants herein amend claims 20 and 21 to recite "an isolated protein molecule". The specification (e.g., page 20, lines 9-13, as well as Examples 1-3) discloses procedures for isolation and purification of proteins. Applicants now submit that this rejection is traversed.

Rejections under 35 USC §112

Claim 10 is rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which the Applicants regard as the invention. Specifically, the Examiner alleges that the phrase "functionally equivalent" is vague and indefinite.

To address this rejection, Applicants herein amend claim 10 to recite:

A structure as claimed in claim 1 which comprises at least one affinity module which has two or more domains capable of binding to the same binding partner and at least one affinity module which has two or more different affinity domains.

Applicants submit that this amendment is supported in the specification at pages 2-3 and page 6, lines 6-9. Accordingly, Applicants submit this rejection has been overcome and respectfully request the Examiner withdraw the rejection.

Claims 11, 13 and 19 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states that phrase "derived" in claims 11, 13 and 19 is vague and indefinite.

To address the rejection, Applicants herein amend claim 11 to recite that the affinity domains comprise a modified or unmodified domain of a naturally occurring bacterial receptor. Claims 13 and 19 are amended similarly and recite that the affinity domain "comprises a modified B domain of SPA", and that

"one of the affinity domains comprises a modified bacterial receptor domain", respectively. Applicants submit that these amendments clarify that the affinity domains may be naturally occurring or modified molecules as explicitly disclosed in the specification at page 5, lines 9-21 and Figure 2. Moreover, various methods of modification are known in the art and disclosed in the specification. For example, at page 10, lines 19-23, Applicants disclose that the modifications include stabilization of a domain by substituting one or more native (naturally occurring) asparagine residues. Further modifications of the affinity domains are disclosed in the present specification at least at page 12, lines 14-18. Accordingly, Applicants submit that this rejection is overcome.

Claims 20 and 21 are rejected under 35 USC §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which the Applicants regard as their invention. Specifically, the Examiner indicates that the phrase "substantially the same" is vague and indefinite.

To address this rejection, the Applicants herein amend claims 20 and 21 as follows:

20. (Currently Amended) An isolated protein molecule having the amino acid sequence of SEQ ID NO:2 or variants thereof, said variants having modified domains wherein said modified domains have at least 80% of the binding affinity of SEQ ID NO:2 for SPA.

21. (Currently Amended) An isolated protein molecule having the amino acid sequence of SEQ ID NO:3 or variants thereof, said variants having modified domains wherein said modified domains have at least 80% of the binding affinity of SEQ ID NO:3 for SPA.

Applicants submit that support for these amendments can be found at least at page 14, lines 11-15 of the present specification. Accordingly, Applicants submit this rejection has been overcome and respectfully request the rejection be withdrawn.

Rejections under 35 USC §102

Claims 1-13, 17-19 and 24-25 are rejected under 35 USC §102(b) as being anticipated by Nord et al. Specifically, the Examiner states that Nord et al. disclose small protein domains, capable of specific binding to different target proteins, called affibodies, fused to bacterial receptor domain Z, derived from Staphylococcal protein A. Applicants respectfully traverse the rejection.

The present invention relates to a self-assembled biomolecular structure comprising affinity modules that have at least two affinity domains which may be the same or different. At least one affinity domain within each affinity module has

specific and exclusive affinity for an affinity domain within another affinity module. "Specific and exclusive affinity" between affinity domains is discussed in the present specification at least at page 6, lines 25-36. The term as used in the present application indicates that within the system each affinity domain has a clearly identifiable affinity partner with which it interacts much more strongly than any other domain present.

In contrast, Nord et al. disclose small protein domains that were designed by randomization of 13 solvent-accessible surface residues of a stable α -helical bacterial receptor domain Z, derived from staphylococcal protein A. Nord et al. designed the binding proteins as an alternative framework to antibodies in therapeutic applications. This reference further discloses that such alternative frameworks can include Staphylococcal protein A. Particularly, Nord et al. used phage display to select novel binding proteins from combinatorial libraries of the one-domain SPA analogue Z.

Nord et al. does not teach or suggest a self-assembled biomolecular structure comprising affinity modules having at least two affinity domains which may be the same or different, nor does Nord et al. disclose the presently claimed feature of

"specific and exclusive affinity for an affinity domain within another affinity molecule."

Accordingly, the Applicants submit that this rejection has been overcome, and respectfully request the rejection be withdrawn.

Claims 20 and 21 are rejected under 35 USC §102(b) as being anticipated by WO 95/19374 to Nilsson et al. Specifically, the Examiner states that Nilsson et al. discloses Z protein variant 22 and Z protein variant 17 which have 76.7 and 78.3 percent identity to SEQ ID NO: 2 and 3 of the instant invention, which allegedly fall into the "variant" language recited in these claims. Applicants respectfully traverse the rejection.

To address the rejections, Applicants herein amend Claims 20 and 21 as follows:

20. (Currently Amended) An isolated protein molecule having the amino acid sequence of SEQ ID NO:2 or variants thereof, said variants having modified domains wherein said modified domains have at least 80% of the binding affinity of SEQ ID NO:2 for SPA.

21. (Currently Amended) An isolated protein molecule having the amino acid sequence of SEQ ID NO:3 or variants thereof, said variants having modified domains wherein said modified domains have at least 80% of the binding affinity of SEQ ID NO:3 for SPA.

Thus, in amended claims 20 and 21, "variants" are recited to have modified domains having at least 80% of the relevant binding affinity.

In contrast, Nilsson et al. discloses Z protein variant 22 and Z protein variant 17. However, neither Z protein variant 22 nor Z protein variant 17 is disclosed to exhibit at least 80% of the binding affinity of the Z_{8G} or Z_{6S} molecule for SPA.

Accordingly, Applicants submit that Nilsson et al. does not teach or suggest the claimed features of claims 20 and 21, and that Nilsson et al. does not anticipate the present claims. Therefore, Applicants submit the current rejection has been overcome and respectfully request the Examiner to withdraw the rejection.

Applicants now submit that the application is in condition for allowance, and reconsideration and a timely Notice of Allowance is earnestly solicited.

If the Examiner believes a telephone conference would aid in the continued prosecution of this application, the Examiner is invited and encouraged to contact Applicants' representative at the telephone number listed below.

Any fees due with this Reply may be charged to Deposit Account **23-1665** under Customer Number **27267**.

Respectfully submitted,

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